JAN - 7 2010

K 091182

# 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS IN ACCORDANCE WITH SMDA OF 1990

DATE OF APPLICATION: 2009, April 15

Submitted by: Champions Implants GmbH
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## 1. DEVICE DESCRIPTION

Trade Name: MIMI® 1-Piece Precision Implant
Common Name: Dental Implant System

The MIMI® 1-Piece Precision Implant is a one piece endosseous dental implant. The thread lengths are 10mm to 16mm. The diameters are 4,0mm and 4,5mm.

## 2. CLASSIFICATION

| | | |
|---|---|---|
| **Device:** | Dental Implant System | |
| **Panel:** | 872 | |
| **Product Code:** | DZE | |
| **Device Class:** | 2 | |
| **Regulation Number:** | 3640 | |

## 3. INTENDED USE

The Champions Implants MIMI 1-Piece Precision Implant is intended to support single or multi-unit restorations in both long-term and temporary applications throughout the maxillary and mandibular arches. The MIMI 1-Piece Precision Implant is indicated for immediate loading when there is good primary stability and an appropriate occlusal load.

## 4. SUBSTANTIAL EQUIVALENCE

- The MIMI® 1-Piece Precision Implant System is substantially equivalent to the Zimmer One-Piece Implant, 3,7mm and 4,7mm, K063523.

## 5. BIOCOMPATIBILITY

The biocompatibility is guaranteed by fulfilling the requirements of ISO 5832-2:1999, ISO 5832-3-3:1996, ISO 5832-11:1994 and is also used in following 510(k):

- K063523

Champions Implants GmbH's Dental Implant Screws are only made out of the in ISO 5832-2:1999, ISO 5832-3-3:1996 and ISO 5832-11:1994 mentioned Raw Materials.

## 6. STERILIZATION

Champions Implants GmbH delivers all MIMI® 1-Piece Precision Implant Screws in sterile conditions. The sterilization process is validated based on ISO 11137:2006.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Champions Implants GmbH
Mr. Marcus Weinacker
CEO
MZQ Managementberatung
Jahnstrasse 14
Tuningen, Baden-Wuerttemberg
GERMANY 78609

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Re: K091182
Trade/Device Name: Champion Implants MIMI 1-Piece Precision Implant
Regulation Number: 21CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: December 18, 2009
Received: December 23, 2009

Dear Mr. Weinacker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091182

Device Name: Champions Implants MIMI 1-Piece Precision Implant

## Indications For Use:

The Champions Implants MIMI 1-Piece Precision Implant is intended to support single or multi-unit restorations in both long-term and temporary applications throughout the maxillary and mandibular arches. The MIMI 1-Piece Precision Implant is indicated for immediate loading when there is good primary stability and an appropriate occlusal load. The MIMI 1-Piece Precision Implants have diameters from 4,0 to 4,5mm and are available in length of 10 to 16mm.

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED9

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Lori Madey for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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